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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/519,202

08/08/2005

Todd M Boyce

525400-344

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01/28/2010

DORSEY & WHITNEY LLP
INTELLECTUAL PROPERTY DEPARTMENT
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MINNEAPOLIS, MN 55402-1498

EXAMINER

SHAHRESTANI, NASIR

ART UNIT

PAPER NUMBER

3737

MAIL DATE

DELIVERY MODE

01/28/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/519,202	Applicant(s) BOYCE ET AL.	
	Examiner NASIR SHAHRESTANI	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 and 35-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 and 35-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 11/18/2009 have been fully considered but they are not persuasive.

Applicant regards the objection to claims 7, 30 and 31 as improper. Examiner respectfully disagrees with applicant's remarks. A depending claim must further limit a parent claim, and as such, a claim depending from a method claim must provide an additional step to the parent method. Claims 7, 30 and 31 do not provide an additional step and are thus not further limiting. Objection to the claims is maintained.

In view of applicant's amendment to claims 24 and 32, rejection of claims 24-29, 32, 33, 35 and 36 under 35 USC 101 has been withdrawn.

With regards to rejection of claims 1-8, 10-18, 20-33, 35 and 36, applicant argues that Morris (primary reference of record) does not teach "using a three-dimensional imaging scan". Examiner respectfully disagrees with applicant's remarks. As previously stated, the Morris reference teaches a clear assessment of donor bone prior to implantation, done by a user. The claim language provides a broad limitation of "three-dimensional imaging" without a suggestion as to what entity is providing such imaging. Hence, it is reasonable to suggest that a user is capable of providing a "three-dimensional imaging scan" through visual assessment. Applicant is invited to provide specific language in relation to said "three-dimensional imaging scan", consistent with the disclosed specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8, 10-18, 20-33, 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris et al. (U.S. 6,458,144 B1) in view of Dore et al. (U.S. 2003/0236473 A1).

Morris et al. teach a method for manufacturing skeletal implant (see title) wherein a donor bone (element 14) taken from human or animal cadaver is provided along with evaluating the suitability of the bone and/or dowel for implant use after each step of the manufacturing process is provided (see abstract). It can be deduced that the process is done, at least, by a human user/manufacture which is considered to be an entity capable of three-dimensional imaging, within the broadest reasonable interpretation of the claimed language, which then

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provides assessment and judgment on the suitability of the bone for implant based on measured parameters (col. 8 lines 12-17). Regarding claim 3, Morris et al. further teach wherein the implant configuration is marked (length marker 72) on the donor bone. Regarding claims 4 and 5, Morris et al. teach the formulation of a cutting plan (by the user/manufacture) utilizing a cutter (dowel cutter 24) to perform the cutting into an implantable configuration. Regarding claims 6-8, the cutting plan, as mentioned before is preformed by a user/manufacture which is clearly capable of computing. It can hence be deduced that Morris et al. teach that the cutting plan is formulated from a computer based model, being scalable and done manually. Regarding claim 33, it can be said that a user/manufacture comprises at least a biological neural network.

Morris et al. however do not teach the use of a device which would provide a three-dimensional imaging scan of the donor bone.

Dore et al. teach high precision modeling of a body part using a 3D imaging system (see title) wherein various 3D imaging modalities such as MRI, SPECT and PET are utilized to provide data regarding cortical bone thickness for implant suitability (fig. 1), which is as indicated by the specification provided by applicant, a parameter other than overall size, for determining donor bone suitability.

It would have been obvious to one of ordinary skill in the art to have modified Morris et al. and to have provided the teaching of Dore et al. in order to provide more accurate implant assessment by using MRI, SPECT, or PET techniques.

Regarding claims 25-29, the improvement of image accuracy utilizing more advanced MRI, SPECT, PET techniques are obvious imaging improvements to those of ordinary skill in the art.

Claims 9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris et al. (U.S. 6,458,144 B1) in view of Dore et al. (U.S. 2003/0236473 A1) as applied to claims 1 and 5 above, and further in view of Ateshian et al. (U.S. 6,459,948 B1).

Morris et al. teach the claim limitations as described above but do not teach wherein the donor bone is cut by an automated device.

Ateshian et al. teach a method and apparatus for manufacturing prosthesis (see title) wherein automated/electronic means are provide to provide the manufacturing process (numerically controlled fabrication means 21).

It would have been obvious to one of ordinary skill in the art at the time of invention to have modified Morris et al. in view of Dore et al. and to have incorporated the automated manufacturing process of Ateshian et al. to provide for furthered accuracy in the donor bone cutting/fabrication process.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NASIR SHAHRESTANI whose telephone number is (571)270-1031. The examiner can normally be reached on Mon.-Thurs: 7:30-5:00, 2nd Friday: 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit
3737

/Nasir Shahrestani/
Examiner, Art Unit 3737